Knowledge Acquisition Session Report
NCI – DCP Protocol Information Office

Session Date: June 13, 2000   **Session Time:** 1:00 – 3:00 P.M.

Session Topic: PIO Information Processes and Procedures

Knowledge Analysts: Bill McCurry, Robert Harding, ScenPro, Inc.; Lisa Chatterjee, Oracle

Organization: Protocol Information Office, NCI Division of Cancer Prevention

Session Location: Rockville, Maryland

Type of Session:
X____ Interview   _____ Task Analysis   _____ Scenario Analysis
_____ Concept Analysis   _____ Observation   _____ Structured Interview
_____ Other:

Documentation: KA Session Report

General Topic Area

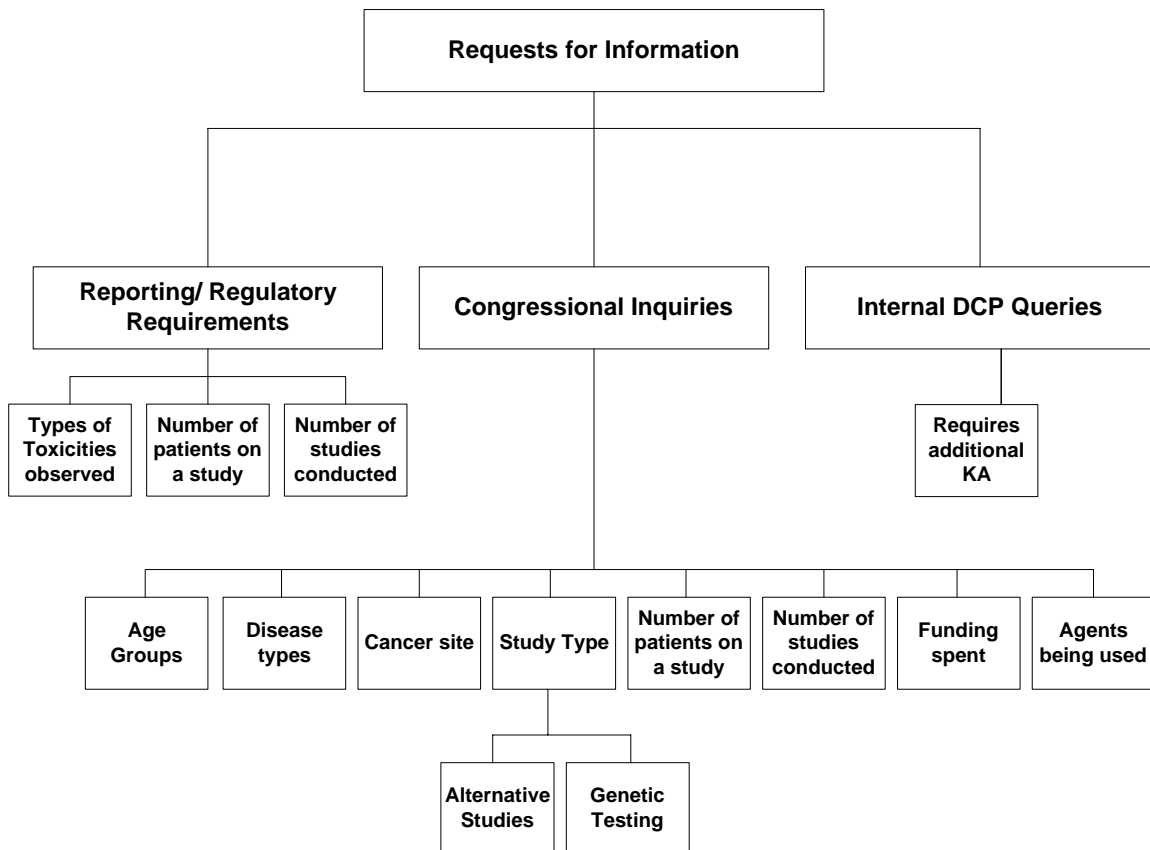Protocol Information Management System user roles and query topics

Session Objective

Identify PIMS information users and most common query topics

Report Summary

PIMS (Protocol Information Management System) will contain protocol information on cancer prevention studies. DCP (Division of Cancer Prevention) personnel need protocol information to complete their tasks. DCP contractors and individuals in other NCI (National Cancer Institute) areas also require protocol information. Currently, the PIO (Protocol Information Office) spends two minutes to an hour answering each inquiry. PIMS users will be able to access protocol information via query mechanisms connected directly to PIMS. PIO personnel identified the user roles and user groups that most commonly require DCP protocol information. The first version of PIMS will not include all the information needed by all users. PIO staff identified the most common query topics and provided examples.

Requests for Information

Periodically, the DCP receives requests for information from members of Congress or other external government organizations. These inquiries are on a number of study-related topics. Types of inquiries are illustrated in the diagram below.
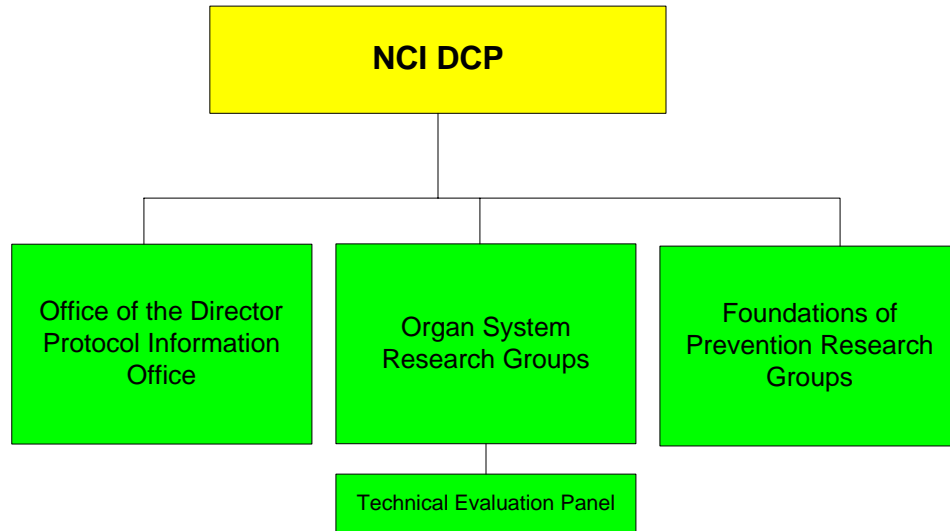
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                        │ Requests for Information  │
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│ Reporting/Regulatory│  │ Congressional       │  │ Internal DCP Queries│
│ Requirements        │  │ Inquiries           │  │                     │
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Reporting/Regulatory Requirements
- Types of Toxicities observed
- Number of patients on a study
- Number of studies conducted

Congressional Inquiries
- Age Groups
- Disease types
- Cancer site
- Study Type
  - Alternative Studies
  - Genetic Testing
- Number of patients on a study
- Number of studies conducted
- Funding spent
- Agents being used

Internal DCP Queries
- Requires additional KA

Protocol Information Management System Inquirers

The Division of Cancer Prevention (DCP) Protocol Information Management System (PIMS) will provide centralized storage and management of protocol information. PIMS will allow system users to access this information through query mechanisms connected directly to PIMS.

PIO personnel identified the user roles and user groups that most commonly require DCP protocol information. The first version of PIMS will not include all information needed by all users. However, later versions may meet more information needs.

Division of Cancer Prevention Inquirers

Specific DCP personnel in the Office of the Director, the research groups and the review committees require access to protocol information. Figure 1 illustrates the DCP areas with users of protocol information.

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│ Office of the │   │  Organ System │   │ Foundations of│
│   Director    │   │Research Groups│   │  Prevention   │
│   Protocol    │   │               │   │   Research     │
│ Information   │   │               │   │    Groups     │
│    Office     │   │               │   │               │
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                    │ Panel         │
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Figure 1: DCP Areas From Which Protocol-Related Queries Originate

Specific positions/ roles within each DCP area generate most of the inquiries. Some position/ roles are common to multiple areas. Table 1 identifies each user position/ role within its area.

Position/ Role	Office of the Director DCP-PIO	Technical Evaluation Panel	Biometry Research Group	Community Oncology and Prevention Trials Research Group	Chemopreventive Agent Development Research Group	Nutritional, Basic Prevention, Biomarkers, Early Detection Research Science Groups	Organ System Research Groups
PIO Head							
Assistant to the Director							
PIO Protocol Specialist							
TEP Chair							
TEP Executive Secretary							
TEP Member							
PRC Member							
Project Officer for Drug Repository							
Protocol Safety Review Board Member							
Research Group Nurses							
Statistical Review Coordinator							
Project Officer							
Reviewers							
Program Directors							
Intramural Principal Investigator							
Research Group Chief							
Medical Monitor							

Table 1: PIMS Inquirers Within the Division of Cancer Prevention

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Non-Division of Cancer Prevention Inquirers

PIO staff answers protocol-related queries from a several areas outside DCP. Other NCI groups require DCP protocol and/or funding information. NCI contractors require protocol information in order to support DCP. Figure 2 shows non-DCP areas with users of protocol information.
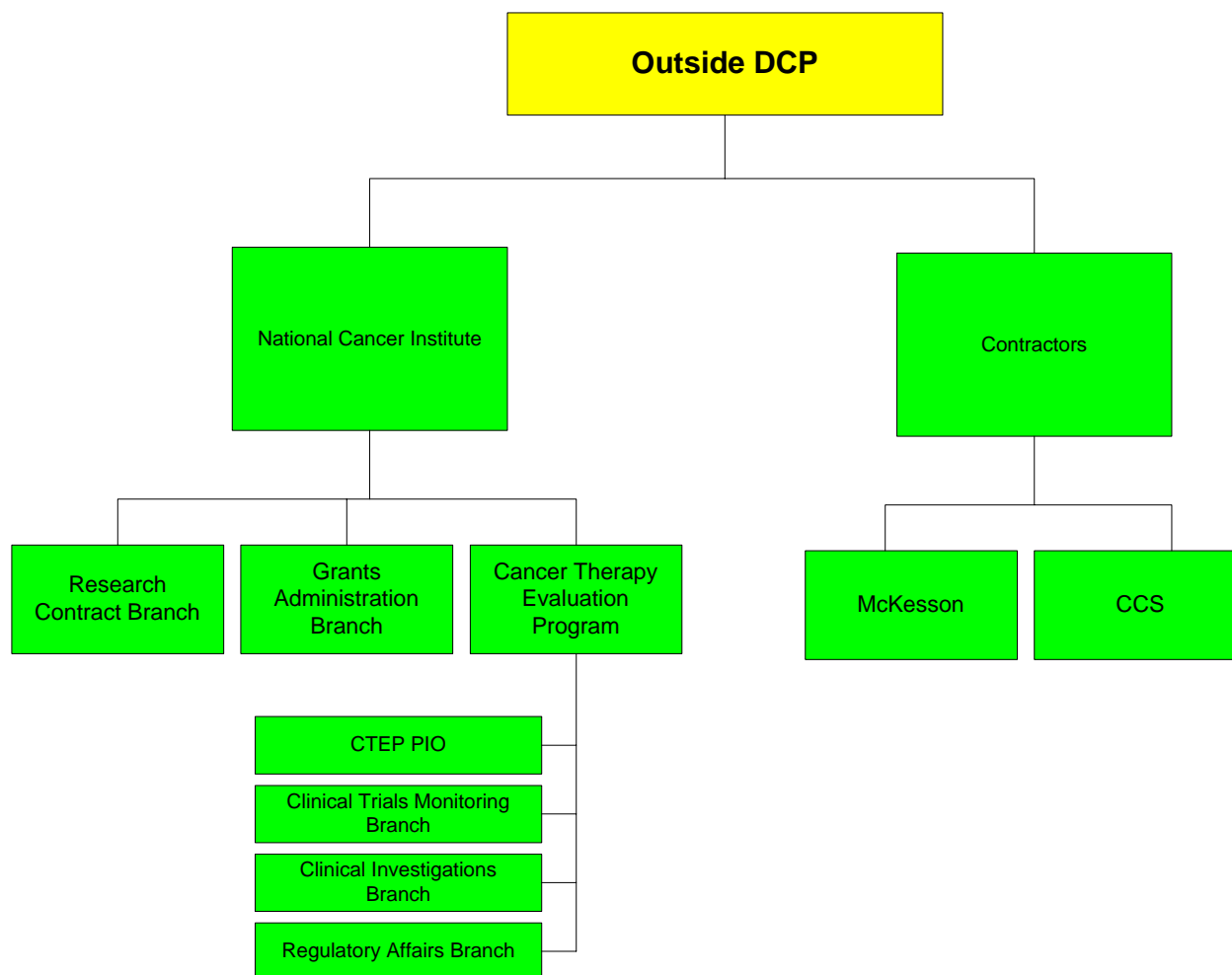

Figure 2: Non-DCP Areas From Which Protocol-Related Queries Originate

Specific positions/ roles within other NCI groups and contractor groups generate most of the non-DCP inquiries. Table 2 identifies each user position/ role within its area.

Position/ Role	CTEP -PIO	Clinical Trials Monitoring Branch	Regulatory Affairs Branch	Clinical Investigations Branch	Research Contracts Branch	Grants Administration Branch	CCS	McKesson
PIO Head								
PIO Protocol Specialist								
Deputy Head of CTEP-PIO								
Medical Monitor								
Cooperative Groups Program Director								
Monitors								
Reviewers								
Contract Officer								
Grant Specialist								
Regulatory Specialist								
Liaison to PIO								
Clinical Research Associate								
Agent Expert								
Repository Manager								
Repository Staff								

Table 2: PIMS Inquirers Outside the Division of Cancer Prevention

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Query Topics

Inquirers ask a variety of questions regarding prevention studies. PIO staff identified which topics are addressed most often. The DCP PIO often receives inquires about the following topics:

- Protocol information
- Agent information
- Disease Type
- Cancer Type
- Information needed by review boards/ committees
- Up-to-date contact information

Additional KA is required on the topics of queries. Specific topics needing additional KA include:
- Adverse Event Reporting
- Funding

Proposed System Requirements

Following is a list of proposed system requirements based on conversations with PIO staff. System should provide:
- Ability to identify duplicate documents
- A Mechanism for independent PIO data entry
- Ability to track non-cooperative group concepts and protocols
- Ability to forward information to CCOP (Community Clinical Oncology Program) Program Directors
- Ability to forward information to contract Project Officers
- Ability to generate and track acknowledgement letters (currently forwarded via E-Mail)
- Ability to forward IND related data to CCSA
- Mechanism for extracting the following information from existing CCSA data resources:
    - Studies awarded
    - Protocols received
    - Status Reports
    - Study Review Status and location
    - Current accrual rate
    - Serious Adverse Event(s)
    - Study Status (Open/ Closed)
    - Date last updated
    - Quarterly report status
    - Annual report status
    - FDA approval status
    - IND study (Yes/ No)
    - IND number
    - IND sponsor
- Provide high-level information to Project Officers including:

- Number of trials by disease (Active/ Completed)
- Issues related to a particular agent
- Issues related to a particular target organ
- Issues related to a particular Bio-marker

Current Database Capabilities

- CCOP IMS database has a concept of a protocol acknowledgement letter that is sent to the head of the research base

User Issues

- To what extent will the new DCP system connect with the CTEP system?
- Will the new system be independent from CTEP PATS?